

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 3

#### REMARKS

Claims 1-3 are pending in the instant application. Claims 1-3 have been rejected. Claims 1-3 have been amended. No new matter has been added by these amendments to the claims. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Rejection of Claims Under 35 U.S.C. 112, Second Paragraph

Claims 1-3 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner suggests that claim 1 is unclear and indefinite with respect to the specific nucleotide sequences of the cited mutations due to use of the open comprising language and the term a "variant". Applicants have amended claim 1 to remove the open comprising language. Thus, withdrawal of this rejection with respect to claim 1 is respectfully requested.

The Examiner also suggests that claims 2 and 3 are unclear and incomplete. Applicants have amended claims 2 and 3 to make it clear that the DNA samples are screened for the presence of the variant genes, as suggested by the Examiner and as taught in the

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 4

specification as filed. Accordingly, withdrawal of this rejection with respect to claims 2 and 3 is respectfully requested.

## II. Rejection of Claims Under 35 U.S.C. 102(b) and 102(e)

The rejection of claims 2 and 3 under 35 U.S.C. 102(b) as being anticipated by Weber et al. has been maintained. The Examiner suggests that since the present method does not involve specifically screening for specific mutations, the prior art which teaches a method of detecting mutations predictive of hereditary non-polyposis colorectal cancer anticipates the instant invention. Applicants respectfully traverse this rejection.

Applicants have amended claim 1, from which claims 2 and 3 depend, to specify four specific mutant genes. Claims 2 and 3 have also been amended to specify that the present invention involves screening for the presence of one of those four mutants. Nowhere does this prior art reference teach or suggest screening for the presence of these four specific gene mutations. Accordingly, this reference cannot anticipate the claims as amended and withdrawal of the rejection is respectfully requested.

The rejection of claims 2 and 3 under 35 U.S.C. 102(e) as being anticipated by Liskay et al. has been maintained. The Examiner suggests that since the claims language does not specify

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 5

screening for the presence of specific mutations, the presence or absence is thus being claimed and Liskay et al. teach a method for detection of mutations of MLH1 and MSH2 genes. Applicants respectfully traverse this rejection.

As discussed *supra*, Applicants have amended claims 1-3 to recite the screening for the presence of four specific mutations. Liskay et al. fail to teach screening for the presence of these four specific mutations as claimed. Accordingly, this reference cannot anticipate the claims as amended and withdrawal of this rejection is respectfully requested.

### III. Conclusion

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 6

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

*Jane Massey Licata*

Jane Massey Licata  
Registration No. 32,257

Date: April 6, 2001

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 7

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 1, 2 and 3 have been amended as follows:

1. (amended) A variant human MLH1 or MSH2 gene ~~comprising~~  
selected from the group consisting of hMLH1 mutant 1, hMSH2 mutant  
1, hMSH2 mutant 2 ~~or~~ and hMSH2 mutant 3.

2. (amended) A method of diagnosing hereditary non-polyposis  
colorectal cancer in a patient comprising:

(a) obtaining a DNA sample from a patient; and

(b) screening the DNA sample for the presence of a  
variant human MLH1 or MSH2 gene of claim 1, wherein the presence of  
the variant gene is indicative of hereditary non-polyposis  
colorectal cancer.

3. (amended) A method for predicting susceptibility of a  
patient to developing hereditary non-polyposis colorectal cancer  
comprising:

(a) obtaining a DNA sample from a patient: and

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
Page 8

(b) screening the DNA sample for the presence of a variant human MLH1 or MSH2 gene of claim 1, wherein the presence of the variant gene is indicative of a susceptibility to hereditary non-polyposis colorectal cancer.